UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE BRISTOL-MYERS SQUIBB CO. SECURITIES LITIGATION	07 Civ. 5867 (PAC) **FILED ELECTRONICALLY**

REPLY MEMORANDUM OF LAW OF BRISTOL-MYERS SQUIBB COMPANY IN SUPPORT OF MOTION TO DISMISS

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Dated: New York, New York
January 7, 2008

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MISCELLANEOUS

Bristol-Myers Squibb Company ("BMS" or the "Company") submits this reply memorandum of law and the Second Declaration of Lorin L. Reisner ("Reisner Sec. Decl.") in further support of its motion to dismiss the Amended Complaint ("Am. Complaint").

PRELIMINARY STATEMENT

BMS demonstrated in its opening memorandum ("BMS Mem.") that the Amended Complaint fails to state a claim because the Company's public filings provided accurate and appropriate disclosure as a matter of law. BMS expressly disclosed: (1) the "significant risk" that regulatory approval of the proposed Plavix litigation settlement would not be obtained; (2) that Apotex could launch a competing generic product in the absence of a settlement; and (3) that generic competition would have serious adverse financial consequences. BMS Mem. 5, 9-16; Reisner Decl. Exs. E, F, G.

In their opposition memorandum ("Pl. Mem."), plaintiffs argue primarily that the Company's statements that it would "vigorously pursue" enforcement of its patent rights if the litigation went forward and that Apotex could launch a generic product "at risk" were false and misleading. Pl. Mem. 1, 12-14, 17. Plaintiffs contend that the Company was required to provide additional details concerning contingent terms of the proposed Plavix settlement, such as damages and provisional remedy limitations that would apply in the event that the settlement did not receive regulatory approval. Pl. Mem. 1-2, 11-18. That argument is incorrect as a matter of law and BMS satisfied its disclosure obligations for the following reasons:

First, the challenged statements were entirely truthful and accurate. BMS did vigorously pursue enforcement of its patent rights. BMS sought and obtained a preliminary injunction within 23 days of the Apotex launch. BMS vigorously presented its case at trial and prevailed. BMS continues to press vigorously for additional relief. BMS Mem. 11-12. Similarly, the statement that "Apotex could launch a generic clopidogrel product at risk," *id.* 5;

Reisner Decl. Ex. E, was entirely truthful and accurate. The Apotex launch was at risk of being preliminarily enjoined and was enjoined prior to the 180-day exclusivity period that otherwise would have applied under the Hatch-Waxman Act. The launch was at risk of being permanently enjoined and was permanently enjoined. The launch also was at risk of exposing Apotex to the payment of substantial damages and Apotex remains at risk of being ordered to pay substantial damages. BMS Mem. 12-13; *see infra* at 4-5.

Second, the information that plaintiffs contend should have been disclosed did not make any prior statement by BMS misleading or false. BMS never represented that it would or intended to seek a TRO in advance of a launch, or that any level of damages would or could be recovered. Plaintiffs' various contentions as to what analysts or commentators "believed," "assumed," "predicted" or "expected the odds of," Pl. Mem. 1, 9, 15; Am. Complaint ¶¶ 91, 93, 98, 102, ignore the Company's *actual disclosures*, as well as the inherent uncertainties of obtaining provisional relief or enhanced damages. Plaintiffs also ignore the repeated cautionary language in BMS public disclosures that it was "not possible . . . reasonably to assess the outcome of this lawsuit or the timing of generic competition for Plavix." BMS Mem. 5; Reisner Decl. Exs. E, F, G. In fact, Judge Stein's determination that Apotex had raised a "substantial question" as to the validity of the Plavix patent, *Sanofi-Synthelabo v. Apotex, Inc.*, 488 F. Supp. 2d 317, 330 (S.D.N.Y. 2006), demonstrated that any request for enhanced damages almost certainly would have been rejected and that prospects of a pre-launch TRO were highly questionable. Having made no promises or representations with respect to seeking a TRO or obtaining any level of damages, BMS had no legal duty to disclose contingent (and confidential) settlement terms relating to those issues. *See infra* at 5-7.

Third, plaintiffs misconstrue the applicable legal standard. There is no duty to provide all information that an analyst might find interesting for assessing risks. Pl. Mem. 1, 9, 14-15; Am. Complaint ¶¶ 91, 93, 98, 102 (referring to analyst "odds," what analysts "opined," "assumed" or "expected" was a "possibility"). No further disclosure was required. *See infra* at 7-8.

Plaintiffs' argument that the Company had an obligation to disclose the existence of alleged "secret side agreements" (which the Company does not believe and never has believed existed), Pl. Mem. 3, 18-19, is incorrect for similar reasons. This alleged non-disclosure did not render any previous BMS statement misleading or false, including the statement that there was a "significant risk" that regulatory approval would not be obtained. In any event, BMS promptly disclosed the Antitrust Division investigation when it came to the Company's attention. No further legal obligation to disclose alleged uncharged wrongful conduct existed, particularly where the risks posed by such alleged wrongdoing previously had been disclosed. *See infra* at 8-9.

Plaintiffs' arguments concerning loss causation and scienter, Pl. Mem. 20-24, 32-39, also fail. Plaintiffs cannot demonstrate loss causation because the stock price declines identified in the Amended Complaint were linked to disclosed risks (regulatory disapproval, Apotex launch). Plaintiffs also cannot establish a "strong inference" of scienter based on the obvious non-culpable reasons for the alleged non-disclosures. *See infra* at 9-10.

ARGUMENT

I. THE COMPANY'S DISCLOSURES WERE ACCURATE AND APPROPRIATE AS A MATTER OF LAW.

The principal argument asserted by plaintiffs is that BMS had an obligation to publicly disclose contingent settlement terms relating to provisional relief and damages limitations,

because in the absence of such information, the Company's statements that it would "vigorously pursue" enforcement of its patent rights if the litigation went forward, and that Apotex could launch a generic product "at risk" were false and misleading. Pl. Mem. 1, 11-14, 17. That argument fails as a matter of law for the following reasons.

First, the challenged statements were entirely truthful and accurate. BMS did vigorously pursue enforcement of its patent rights. BMS sought and obtained a preliminary injunction within 23 days of the Apotex launch. *Sanofi-Synthelabo v. Apotex, Inc.*, 488 F. Supp. 2d 317, 321 (S.D.N.Y. 2006). BMS vigorously presented its case at trial and prevailed. *Id.*, 492 F. Supp. 2d 353, 397-98 (S.D.N.Y. 2007). BMS continues vigorously to press for additional relief from Apotex. Reisner Decl. Ex. W (current docket sheet).[1] The Apotex launch obviously was at risk. The launch was at risk of being preliminarily enjoined and was preliminarily enjoined before the expiration of Apotex's 180-day period of exclusivity under the Hatch-Waxman Act. *Sanofi-Synthelabo*, 488 F. Supp. 2d at 344. The launch was at risk of being permanently enjoined and was permanently enjoined. *Id.*, 492 F. Supp. 2d at 356. Apotex was at risk and remains at risk of being ordered to pay substantial damages based on its infringing conduct. *Id.* at 397. As Judge Stein expressly observed, Apotex had commenced an "at-risk launch," *id.*, 488 F. Supp. 2d at 344, and other cases similarly have recognized that an "at-risk" launch occurs where, as was the case at the time of the challenged disclosures, the court had "not yet rendered a decision" on the "underlying infringement claim." *Altana*

[1] Plaintiffs' reliance on *In re Gulf Oil/Cites Serv. Tender Offer Litig.*, 725 F. Supp. 712 (S.D.N.Y. 1989), Pl. Mem. 13, is misplaced. There, the court held that a press release stating that a defendant intended to contest an injunction "vigorously" could be actionable where it was alleged that defendant actually "had no intention of contesting" the injunction and had done nothing to contest the injunction. *Id.* at 750. In stark contrast, here BMS actively and aggressively pursued its patent rights.

Pharma AG v. Teva Pharms. USA, Inc., No. 04-2355 (JLL), 2007 U.S. Dist. LEXIS 67285, at *13 (D.N.J. Sept. 6, 2007).[2] Where, as here, the challenged statements are demonstrably true and accurate, they cannot be actionable as a matter of law. BMS Mem. 12 (citing cases).

Second, the alleged non-disclosures did not make any prior statement by BMS misleading or false. BMS never represented that it would or intended to seek a TRO in advance of a launch or that any particular level of damages could or would be recovered. BMS therefore had no duty to publicly announce the contingent provisional remedy and damages limitations. *See In re Progress Energy, Inc. Sec. Litig.*, 371 F. Supp. 2d 548, 553 (S.D.N.Y. 2005) (granting motion to dismiss Section 10(b) claims and observing that defendant had no duty to disclose extent to which alternative minimum tax provisions would reduce its tax burden where prior public filings made no specific assurances as to tax advantages of fuel credits); *In re Citigroup Sec. Litig.*, 330 F. Supp. 2d 367, 378 (S.D.N.Y. 2004) (granting motion to dismiss Section 10(b) claims and observing that defendant had no obligation to disclose that its revenues were "unsustainable" where it had not previously made any specific "projections or revenue predictions"), *aff'd sub. nom*, *Albert Fadem Trust v. Citigroup, Inc.*, 165 Fed. Appx. 928 (2d Cir. 2006); *Debora v. WPP Group PLC*, No. 91 Civ. 1775 (KTD), 1994 U.S. Dist. LEXIS 5830, at *20-*21 (S.D.N.Y. May 5, 1994) (granting motion to dismiss Section 10(b) claims and observing that defendant had no duty to disclose negotiations of a new credit agreement where it had made no previous statement regarding future renegotiation of its debt structure). In fact, contrary to making promises about any type of relief that would be sought or secured, BMS repeatedly cautioned that it was "not possible . . . reasonably to assess the

[2] Plaintiffs completely ignore the *Altana Pharma* case. Plaintiffs ultimately concede that Apotex faced a "risk" in its launch, Pl. Mem. 15 n.6, but weakly assert it was "less than a

outcome of this lawsuit or the timing of generic competition for Plavix." Reisner Decl. Ex. E (March 21, 2006 Form 8-K and press release); *id.* Ex. F (April 27, 2006 press release) (repeating cautionary language); *id.* Ex. G (Form 10-Q filed on May 8, 2006) (same). *See San Leandro Emergency Med. Group Profit Sharing Plan v. Philip Morris Cos.*, 75 F.3d 801, 809-11 (2d Cir. 1996) (affirming dismissal of alleged non-disclosure claims under Section 10(b) based on company's balanced disclosure of "hope, adequately tinged with caution," and holding that company's description of business plans did not require additional disclosure).[3]

Plaintiffs' arguments also are flawed based on their misstatement of the circumstances in which provisional relief and enhanced damages are available. Pl. Mem. 17 (arguing that patent plaintiffs have "rights to secure immediate injunctive relief . . . and treble damages"). In reality, there are no assurances (and BMS provided no assurances) that such relief can be secured under the rigorous and often unpredictable legal standards. Under patent law, enhanced damages generally are not available where an infringer asserts a "good faith and substantial challenge" to the validity of a patent. 7-20 CHISUM ON PATENTS § 20-03[4][b][v][E] (2007). Judge Stein's determination that Apotex raised a "substantial question" as to the

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normal 'at-risk' launch." *Id.*

[3] Plaintiffs' attempt to rely on *Brumbaugh v. Wave Sys. Corp.*, 416 F. Supp. 2d 239 (D. Mass. 2006) and the other cases cited at Pl. Mem. 16-17, is unavailing. Those cases stand for the unremarkable proposition that some disclosures may be so incomplete as to mislead. *See, e.g.*, *Brumbaugh*, 416 F. Supp. 2d at 246-50 (where company "on the brink of extinction" announced "unprecedented revenue growth" based on contracts, it may have been required to disclose that contracts contained no required payments); *McMahan & Co. v. Wherehouse Entm't, Inc.*, 900 F.2d 576, 580-81 (2d Cir. 1990) (statements regarding role of "independent" directors could be misleading where "independent" directors constituted all but one of the "ordinary" directors, "had no independence" and "would never protect the interests of [plaintiffs] except by coincidence"); *In re Time Warner Inc. Sec. Litig.*, 9 F.3d 259, 268 (2d Cir. 1993) (when company announces specific business goal and intended approach, it may have an obligation to disclose other approaches under active and serious consideration).

validity of the Plavix patent, *Sanofi-Synthelabo*, 488 F. Supp. 2d at 330, demonstrates that any claim for enhanced damages almost certainly would have been rejected. For similar reasons, in addition to the standards traditionally applied under Fed. R. Civ. P. 65, the prospects of a TRO also were highly questionable. *See Intel Corp. v. ULSI Sys. Tech.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993) (provisional relief "drastic and extraordinary" remedy).[4]

Plaintiffs' position that contingent terms of a confidential proposed settlement must be disclosed also conflicts with the settled principle that the securities laws should not be interpreted to require the disclosure of sensitive business information, particularly where, as here, it could be used by adversaries in related pending patent litigation to prejudice the Company. *See* Reisner Decl. Exs. X, Y (docket sheets in related patent litigation); Ex. E (BMS description of related patent litigation); *San Leandro*, 75 F.3d at 809 (securities laws should not be interpreted to require disclosure of "sensitive" information that could give competitors unfair advantage); *Canandaigua*, 944 F. Supp. at 1211 (no duty to disclose information that "forc[es] a company to damage its own interests . . . by revealing competitive information").

Third, plaintiffs misconstrue the applicable legal standard. There is no obligation to disclose every detail that an analyst might like for a risk-assessment model. Pl. Mem. 1, 9, 14-15 (referring to analyst "odds," what analysts "opined," "assumed" or "expected" was a "possibility"). Arguments similar to those made by plaintiffs have been squarely rejected. *See*

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[4] BMS certainly is not responsible for what analysts or other commentators might have "opined," "assumed," "believed," or "expected the odds of," Pl. Mem. 1, 9, 15, based on their own assumptions, calculations or beliefs, particularly when those assumptions were at variance with the Company's disclosures. *See In re N. Telecom Ltd. Sec. Litig.*, 116 F. Supp. 2d 446, 458-59 (S.D.N.Y. 2000) (no duty to inform analysts "that their optimistic view was not shared by the company") (quotation omitted); *In re Canandaigua Sec. Litig.*, 944 F. Supp. 1202, 1212 (S.D.N.Y. 1996) (no duty to provide additional disclosure where analysts based projections on their own "assumption" rather than statements by company).

In re SINA Corp. Sec. Litig., No. 05 Civ. 2154 (NRB), 2006 U.S. Dist. LEXIS 71089, at *20 (S.D.N.Y. Sept. 26, 2006) (granting motion to dismiss where risks associated with doing business in China were disclosed and additional detailed information was "not required . . . simply because it may be relevant or of interest to a reasonable investor") (quoting *Resnik v. Swartz*, 303 F.3d 147, 154 (2d Cir. 2002)); *Castillo v. Dean Witter Discover & Co.*, No. 97 Civ. 1272 (RPP), 1998 U.S. Dist. LEXIS 9489, at *29-*30 (S.D.N.Y. June 25, 1998) (no duty to disclose additional details about calculation of broker fees and requiring such disclosure "would engender an almost impossible problem of defining the limits of such a duty").[5]

Plaintiffs' argument that the Company had an obligation to disclose the existence of alleged "secret side agreements" (which the Company does not believe and never has believed existed, BMS Mem. 22), also is incorrect as a matter of law. Even accepting plaintiffs' allegations that alleged oral side agreements existed, the alleged non-disclosures are not actionable because they did not render any previous statement by BMS false or misleading. Plaintiffs argue that the purported secret side agreements increased the risk of non-approval by regulators. Pl. Mem. 19. BMS already had disclosed, however, that there was a "significant risk" that regulatory approval would not be obtained, Reisner Decl. Ex. E, F & G, and that disclosure remained true and accurate. BMS also promptly disclosed the Antitrust Division investigation upon learning of its existence. Reisner Decl. Ex I.[6] There is no legal obligation

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[5] *See also Ieradi v. Mylan Labs., Inc.*, 230 F.3d 594, 600 (3d Cir. 2000) (company not required to disclose exclusive contracts allegedly necessary to "assess the risk" of liability).

[6] Plaintiffs' related argument that the June 25, 2006 press release was misleading because the revised settlement agreement allegedly was not amended in response to "concerns" raised by the regulators, Pl. Mem. 2, 18, is inconsistent with their own pleading, Am.

to make additional disclosure concerning alleged uncharged wrongful conduct, particularly where, as here, the risks posed by such alleged wrongdoing were previously disclosed. BMS Mem. 14, 16 (discussing cases).[7]

II. PLAINTIFFS' ALLEGATIONS OF LOSS CAUSATION AND SCIENTER ARE INSUFFICIENT AS A MATTER OF LAW.

Plaintiffs cannot establish loss causation as a matter of law because the alleged economic harm was linked to disclosed risks: that regulatory approval would not be obtained and that Apotex could launch a competing generic product. BMS Mem. 17-18. Plaintiffs' argument that the alleged loss was caused by a lack of disclosure of settlement terms, Pl. Mem. 4, 32-39, fails as a matter of logic and law because those terms had no independent significance apart from the disclosed risks. Plaintiffs also offer no effective response to the undeniable fact that the price per share of BMS stock traded higher (range of $29.17 to $30.48) in the period following disclosure of the alleged omissions and disposition of the Antitrust Division investigation, than during the purported "Class Period" in which the share price allegedly was "artificially inflated" (range of $21.21 to $25.99). BMS Mem. 20.

Plaintiffs also fail to meet their burden of pleading scienter in a manner that is as "cogent" and "compelling" as the plausible non-culpable explanations for the alleged

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Complaint ¶ 39 (describing BMS attempts to renegotiate agreement "in hopes of securing the regulators' approval") and the plain language of the revised agreement, *id.* at ¶ 40 (describing revised license term); Reisner Sec. Decl. Ex. A (publicly filed copies of initial and amended agreements).

[7] The cases cited by plaintiffs at Pl. Mem. 18-19 are inapposite because the alleged wrongdoing in those cases contradicted specific prior factual statements of the defendants. *See, e.g., Menkes v. Stolt-Nielsen, SA*, No. 3:03 CV 409 (DJS), 2005 U.S. Dist. LEXIS 28208, at * 24-25 (D. Conn. Nov. 10, 2005) (public statements that pricing environment was "tight" and subject to continued "pressure" contradicted by allegations of price-fixing).

non-disclosures. BMS Mem. 21 (quoting *Tellabs Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2509 (2007)). Their attempt to impose plaintiffs' burden on defendants, Pl. Mem. 20, should be rejected as a matter of law, *see, e.g.*, *Novak v. Kasaks*, 216 F.3d 300, 310 (2d Cir. 2000) (plaintiff's burden to plead scienter), and their unsupported assertion that the Company's public statements were "designed" to mislead, Pl. Mem. 22, should be rejected as far less plausible than the reasonable inferences that: (a) BMS did not believe in good faith it had any duty to provide more detailed information about confidential and contingent settlement terms; (b) BMS sought to avoid having confidential and contingent settlement terms used by third parties to the Company's disadvantage; and (c) those making decisions regarding disclosures were unaware of any purported "secret side agreements" relating to the Plavix settlement. BMS Mem. 21-23.

CONCLUSION

For the foregoing reasons and those set forth in the opening memorandum of BMS, the Amended Complaint should be dismissed.

Dated: New York, New York
January 7, 2008

Respectfully submitted,

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